$$\text{Milligrams of minocycline per milliliter} = \frac{A_u \times P_s \times d}{A_s \times 1{,}000 \times 5}$$

where:

A_u = Area of the minocycline peak in the chromatogram of the sample (at a retention time equal to that observed for the standard);

A_s = Area of the minocycline peak in the chromatogram of the minocycline working standard:

P_s = Minocycline activity in the minocycline working standard solution in micrograms per milliliter; and

d = Dilution factor of the sample.

(2) *pH.* Proceed as directed in §436.202 of this subchapter, using the undiluted sample.

[39 FR 19076, May 30, 1974, as amended at 43 FR 11163, Mar. 17, 1978; 44 FR 22058, Apr. 13, 1979; 50 FR 19920, May 13, 1985; 53 FR 32609, Aug. 26, 1988]

§446.165 Oxytetracycline oral dosage forms.

§446.165a Oxytetracycline tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline tablets are tablets composed of oxytetracycline and one or more suitable and harmless, diluents, binders, lubricants, colorings, and coating substances. The potency of each tablet is 250 milligrams of oxytetracycline. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain. The moisture content is not more than 7.5 percent. They shall disintegrate within 1 hour. The oxytetracycline used conforms to the standards prescribed by §446.65(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency, moisture, and disintegration time.

(ii) Samples required:

(*a*) The oxytetracycline used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in §436.106 of this chapter, preparing the sample for assay as follows: Place a representative number of tablets into a high-speed glass blender jar containing sufficient 0.1*N* hydrochloric acid to obtain a stock solution of convenient concentration containing not less than 150 micrograms of oxytetracycline per milliliter (estimated). Blend for 3 to 5 minutes. Remove an aliquot of the stock solution and further dilute with sterile distilled water to the reference concentration of 0.24 microgram of oxytetracycline per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

(3) *Disintegration time.* Proceed as directed in §436.212 of this chapter, using the method described in paragraph (e)(1) of that section.

[43 FR 11163, Mar. 17, 1978; 43 FR 34456, Aug. 4, 1978, as amended at 50 FR 19920, May 13, 1985]

§§446.165b—446.165c [Reserved]

§446.165d Oxytetracycline for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline for oral suspension is oxytetracycline with one or more suitable and harmless buffer substances, preservatives, diluents, colorings, and flavorings. When prepared as directed in the labeling, each milliliter contains 50 milligrams of oxytetracycline. Its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of oxytetracycline that it is represented to contain. Its loss on drying is not more than 2 percent. When reconstituted as directed in the labeling, its pH is not less than 5.5 and not more than 7.5. The oxytetracycline used conforms to the standards prescribed by §446.65(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline used in making the batch for potency, moisture, pH, absorptivity, identity, and crystallinity.

(*b*) The batch for potency, loss on drying, and pH.

(ii) Samples required:

(*a*) The oxytetracycline used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Reconstitute as directed in the labeling. Transfer an accurately measured representative portion of the well-shaken suspension to an appropriate-sized volumetric flask and dilute to volume with 0.1*N* hydrochloric acid to obtain a stock solution of convenient concentration containing not less than 150 micrograms of oxytetracycline per milliliter (estimated). Mix well. Further dilute an aliquot of the stock solution with sterile distilled water to the reference concentration of 0.24 microgram of oxytetracycline per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *pH.* Reconstitute as directed in the labeling and proceed as directed in § 436.202 of this chapter.

[43 FR 11164, Mar. 17, 1978, as amended at 48 FR 51293, Nov. 8, 1983; 50 FR 19920, May 13, 1985]

§ 446.166 Oxytetracycline calcium oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline calcium oral suspension contains oxytetracycline calcium with one or more suitable and harmless buffer substances, suspending and stabilizing agents, flavorings, colorings, solvents, and preservatives suspended in a suitable and harmless vehicle. It may contain *N*-acetyl glucosamine. Each milliliter contains a quantity of oxytetracycline calcium equivalent to 25 milligrams of oxytetracycline. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of oxytetracycline that it is represented to contain. Its pH is not less than 5.0 and not more than 8.0. The oxytetracycline calcium used conforms to the standards prescribed by § 446.66(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The oxytetracycline calcium used in making the batch for potency, moisture, pH, calcium content, identity, and crystallinity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The oxytetracycline calcium used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Transfer an accurately measured representative portion of the sample to an appropriate-sized volumetric flask and dilute to volume with 0.1*N* hydrochloric acid to give a stock solution of convenient concentration containing not less than 150 micrograms of oxytetracycline per milliliter (estimated). Mix well. Remove an aliquot of the stock solution and further dilute with sterile distilled water to the reference concentration of 0.24 microgram of oxytetracycline per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

[43 FR 11164, Mar. 17, 1978 as amended at 43 FR 50677, Oct. 31, 1978; 45 FR 16476, Mar. 14, 1980; 50 FR 19920, May 13, 1985]

§ 446.167 Oxytetracycline hydrochloride capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Oxytetracycline hydrochloride capsules are gelatin capsules